Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-935

MARVIN W. JOHNSON,
Petitioner,

versus

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No.

MARVIN W. JOHNSON,
Petitioner,

versus

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Petitioner, MARVIN W. JOHNSON, respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit entered on October 30, 1978, denying a petition for rehearing directed to that Court's written opinion dated October 3, 1978. The initial Fifth Circuit opinion affirmed judgments of conviction entered by the United States District Court for the Middle District of Florida in a criminal prosecution brought by the United States against the petitioner. The opinion of the United States Court of Appeals for the Fifth Circuit upheld the admissiblity of opinion testimony by the Govern-

ment's chief expert witness as to the legal standard of conduct required of the petitioner. A timely petition for rehearing was denied by the Court of Appeals and judgment was entered. The petitioner now prays that this Court review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

OPINIONS BELOW

The October 3, 1978, opinion of the United States Court of Appeals for the Fifth Circuit is not reported. The unpublished opinion of that Court is set out in the appendix to this petition.

The order of the United States Court of Appeals for the Fifth Circuit denying rehearing is not presently reported. This order is also set out in the appendix to this petition.

JURISDICTION

The opinion of the Court of Appeals was entered on October 3, 1978, affirming the trial court's judgments of conviction. The Court of Appeals denied a timely petition for rehearing on October 30, 1978. On November 22, 1978, Mr. Justice Powell extended the time for filing this petition to and including December 13, 1978. This Court's jurisdiction is invoked under 28 U.S.C. §1254(1).

QUESTION PRESENTED

Whether, in a criminal prosecution for violations of federal statutes implemented by administrative regulations, Rule 704, Federal Rules of Evidence, permits the Government's expert witness to give opinion testimony as to the legal standard of conduct required of the defendant?

STATUTES AND RULE INVOLVED

United States Code, Title 21:

Section 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated–
(a) (2) * * * (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with *current good manufacturing practice* to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; * * *.

* * * * * * * * * *

(c) If it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. (emphasis added).

United States Code, Title 42:

Section 262. Regulation of biological products– Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales

* * *

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the

products for which a license is desired meet *standards,* designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. * * * (emphasis added).

Federal Rules of Evidence:

Rule 704. Opinion on Ultimate Issue.

Testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

STATEMENT OF THE CASE

Petitioner was a defendant in a criminal prosecution instituted in the United States District Court for the Middle District of Florida. After a jury trial, petitioner was found guilty of eleven counts of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a) and 333 (prohibiting the interstate shipping of adulterated or misbranded drugs); the Public Health Service Act, 42 U.S.C. §262(b) and (f) (prohibiting false labels on drug containers); 18 U.S.C. §1001; and the federal conspiracy statute, 18 U.S.C. §371. Judgments of conviction were entered by the District Court and sentences were imposed. The petitioner received two year prison sentences as to Counts One and Two of the indictment and one year sentences as to the remaining counts, each sentence to be served concurrently with the Count One sentence.

The indictment charged the petitioner with criminal activity associated with the management and operation of two

commerical plasmapheresis centers located in central Florida which allegedly occurred between August 1, 1973, to January 10, 1975. During this time period, the petitioner, a licensed medical doctor, was the secretary and medical director of a corporation which owned and operated these centers. Plasmapheresis is a process by which a unit of whole blood is drawn from a donor into a plastic bag. The bag is then placed into a centrifuge and spun so that the heavier red blood cells are separated from the lighter plasma which remains at the top of the bag. The plasma is then drawn off into a separate bag and the red blood cells are reinfused into the donor.

The Food and Drug Administration (FDA) has divided human blood plasma, obtained through the process of plasmapheresis, into two distinct categories: Source Plasma (Human) and fresh human serum. Source Plasma (Human) is defined as plasma collected by plasmapheresis that is intended for further manufacture into injectable products. These products are used for medical purposes. Fresh human serum is plasma with the clotting mechanism removed. The primary use for fresh human serum is in the further manufacture of diagnostic products which are noninjectable and used as laboratory test materials. Source Plasma (Human) and fresh human serum are both "drugs" subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq., and "biological products" subject to the Public Health Service Act, 42 U.S.C. §201 et seq.

Specifically, the Government charged the petitioner and his co-defendants with shipping plasma in interstate commerce which was adulterated as defined in Section 351(a)(2)(B) and (c), misbranded as defined in 21 U.S.C. §352(a), and falsely labeled in violation of 42 U.S.C. §262(b) because the plasma donor was misidentified and the plasma was mislabeled. The petitioner was also charged with mak-

ing a false statement in violation of Section 1001 by his presigning physical examination forms, which examinations were not conducted by a physician. Finally, the petitioner was charged with conspiring to violate the Federal Food, Drug, and Cosmetic Act and Section 1001.

To implement the "current good manufacturing practice" statutory requirement of Section 351(a)(2)(B), the FDA in 1967 promulgated general regulations entitled: Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding of Drugs (GMP), 21 C.F.R. Part 133 (now 21 C.F.R. Part 210). These GMP regulations are applicable to the entire drug industry and are intended to assure that drugs are safe and will have the quality, purity, identity, and strength which they purport or are represented to possess.

In the fall of 1973, the FDA required, for the first time, that plasmapheresis centers drawing injectable products be licensed. Pursuant to 42 U.S.C. §262(d) the FDA promulgated licensing standards entitled: General Biological Products Standards, 21 C.F.R. Part 610, and Additional Standards for Human Blood and Blood Products, 21 C.F.R. Part 640. Subpart E of Part 610 required that plasma and serum be tested for hepatitis. Subpart G of Part 640 set out certain additional standards for Source Plasma (Human), including the requirement that a plasma donor be given a medical examination by a physician prior to his first donation. 21 C.F.R. §640.63.

After the time period of this case, the FDA promulgated specific GMP regulations entitled: Current Good Manufacturing Practices for Blood and Blood Components, 21 C.F.R. Part 606. These GMP regulations for the first time specifically pertained to both Source Plasma (Human) and fresh human serum and required, among other things, pre-donation

medical examinations. 21 C.F.R. §606.160. Parts 610 and 640 were not amended or repealed.

Throughout the course of this litigation, there was complete disagreement between the prosecution and the defense as to which of these regulations defined the statutory "current good manufacturing practice" required by Section 351(a)(2)(B) as to the manufacture of both Source Plasma (Human) and fresh human serum during this time period. The Government argued that the 1973 standards set out in Parts 610 and 640 as well as Part 133 were the current good manufacturing practices required for both types of plasma. The petitioner's position was that the only FDA regulations which described the current good manufacturing practices required by Section 351(a)(2)(B) were the 1967 general Current Good Manufacturing Practices set out in Part 133. The petitioner argued that Parts 610 and 640 were licensing standards and not GMP because those Parts were promulgated pursuant to 42 U.S.C. §262. *See* 39 Fed. Reg. 18614-15 (1974). Furthermore, since the FDA promulgated specific GMP regulations for both types of plasma in 1976 (Part 606) without repealing or amending the 1973 standards, the petitioner argued that Parts 610 and 640 were not the "current good manufacturing practice" required by Section 351(a)(2)(B) but were instead licensing standards. This issue was crucial because the Part 133 GMP regulations were much less stringent than the Parts 610 and 640 standards; and did not specifically require a pre-donation medical examination or hepatitis testing.

In a memorandum of law, the Government advised the trial judge that it intended to elicit expert trial testimony to prove that the 1973 licensing standards were additional "current good manufacturing practices" for both Source Plasma (Human) and fresh human serum, despite the fact that it was not until 1976 that specific Current Good Manufacturing Prac-

tices for all types of plasma were effective. To prove this point, the Government called as its last witness, Dr. Sam Gibson, the Assistant to the Director of the Bureau of Biologics of the FDA. This bureau regulates and licenses plasmaphersis centers.

Dr. Gibson was qualified as an expert witness and, over defense objection, presented opinion testimony as to the conduct, practices, and methods required to be followed by plasmapheresis centers during the time period involved in this case as the Government had predicted in its memorandum of law. Thus, Dr. Gibson was allowed to flesh out with detailed specifics the general black letter provisions of the 1967 GMP regulations (21 C.F.R. Part 133); and to testify in support of the legal position the Government had taken at trial as to what was the "current good manufacturing practice" applicable to this criminal prosecution by echoing the 1973 licensing standards (21 C.F.R. Parts 610 and 640). For example, the following colloquy took place:

> Q [The prosecutor]: * * * [W]hat steps, in your opinion, need to be taken with regard to identification of donors and examination of donors as they would relate to the safety, identity, strength, quality and purity of the products being manufactured?
>
> * * *
>
> A: * * * [B]efore starting on plasmapheresis *it is fundamental to perform a physical examination, have a physician perform this,* to be certain that the patient could provide good plasma * * *.
>
> Q: [W]ith regard to the examination of the donor by a physician, how does the plasmapheresis procedure * * * differ from a donation of whole blood to * * * a blood bank?

> A: [T]he reason that a physical examination is *required* before plasmapheresis and not * * * before a blood donation * * * is because * * * [of] the considerable difference in the shock to the body. (Tr. F-2759, 2764-65) (emphasis added).

Dr. Gibson also testified, over defense objection, as to the necessity and requirements for storing plasma, testing plasma for hepatitis, and the proper packing, labeling, and shipping of plasma (Tr. F-2764-72).

This opinion testimony was highly prejudicial to the petitioner. The requirement of a pre-donation medical examination by a physician was directly related to the false writing charge and the petitioner's participation in the conspiracy. The "good manufacturing practice" described by this witness also related to the other charges brought against the petitioner relating to the adulterated, mislabeled and misbranded shipments of plasma. Significantly, Dr. Gibson's testimony did not differentiate between the requirements applicable to Source Plasma (Human) and fresh human serum.

The significance of this opinion testimony was exacerbated by the trial court's erroneous instruction to the jury that they could consider the 1973 licensing standards and Dr. Gibson's opinion testimony in determining the "current good manufacturing practice" required by Section 351(a)(2)(B). The trial court, over defense objection, instructed the jury:

> * * * You are further instructed that the law also deems a drug to be adulterated if the methods used in or the facilities or controls for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with *current good manufacturing practices* to assure that such drug meets the requirements as to

safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

To implement this position of the law, the Federal Food and Drug Administration has promulgated regulations spelling out the good manufacturing practices. Section 133 of the Code of Federal Regulations was adopted about 1967 and was in effect through the period of the alleged conspiracy. That is, August 1st, 1973, until January 10, 1975.

Section 133, among other things, provides [pertinent excerpts from Part 133 read to the jury].

On November 20th, 1973, Part 600, Part 610 and Part 640 of Title 21 of the Code of Federal Regulations were in effect. The provisions thereof are applicable to the manufacture of source plasma (human) intended for injection. Those regulations provide additional standards designed to ensure the continued safety, purity and potency of such products and other related matters. Pertinent parts of the November, 1973, regulations are [excerpts from Parts 600, 610, and 640 read to the jury].

In considering whether the Government has proved the charges of adulteration of drugs as a result of the alleged failure to operate or administer the facilities * * * *in conformity with good manufacturing practices, you may consider the Federal Regulations, the expert testimony* and the – all the evidence in the case as to the methods used in and facilities and controls used for the

manufacturing, processing, packing or holding of a drug at the establishments * * * (Tr. J-4187-99) (emphasis added).

On appeal, the Fifth Circuit held that the trial court did not abuse its discretion in admitting the expert's opinion testimony.

The underlying legal issue in this case is the distinction between a violation of Section 351(a)(2)(B)'s "current good manufacturing practice" (implemented by Part 133) which invokes criminal penalties, and a violation of 42 U.S.C. §262 (d)'s licensing "standards" (implemented by Parts 610 and 640) which invoke civil or administrative penalties.

REASONS FOR GRANTING THE WRIT

IN A CRIMINAL PROSECUTION FOR VIOLATIONS OF FEDERAL STATUTES IMPLEMENTED BY ADMINISTRATIVE REGULATIONS, RULE 704, FEDERAL RULES OF EVIDENCE, DOES NOT PERMIT THE GOVERNMENT'S EXPERT WITNESS TO GIVE OPINION TESTIMONY AS TO THE LEGAL STANDARD OF CONDUCT REQUIRED OF THE DEFENDANT.

The lower federal appellate courts have been unanimous in holding that Rule 704, Federal Rules of Evidence, permits expert opinion testimony which draws inferences from the facts, even though it goes to the ultimate issue of the case; but Rule 704 does not permit expert opinion testimony which is in the form of a legal interpretation or conclusion as to what the law requires. *See, e.g., United States v. Gutierrez,* 576 F.2d 269, 275 (10th Cir. 1978) (DEA agent permitted to testify as to the meaning of various terms used by narcotics violators and their methods of operation); *Nielson v. Armstrong Rubber Co.,* 570 F.2d 272 (8th Cir. 1978) (plaintiff's expert witness permitted to testify, in products liability

case, that the defendant's manufacturing process caused a defect in an automobile tire); *United States v. Sellers*, 566 F.2d 884 (4th Cir. 1977) (trial judge committed reversible error in excluding defendant's expert testimony as to the identity of the robber in a bank photograph); *United States v. Davis*, 564 F.2d 840, 845 (9th Cir. 1977), *cert. denied*, ___U.S. ___, 98 S.Ct. 733, 54 L.Ed.2d 760 (1978) (Government's expert physician properly permitted to testify that the defendant physician was not prescribing drugs in the usual course of his professional practice in a prosecution for the unlawful distribution of a controlled substance); *United States v. Hearst*, 563 F.2d 1331, 1350-51 (9th Cir. 1977), *cert. denied*, ___U.S. ___, 98 S.Ct. 1656, 56 L.Ed.2d 90 (1978) (Government's expert witnesses permitted to testify that in their opinion defendant entered a bank voluntarily in order to participate in a robbery); *United States v. Milton*, 555 F.2d 1198, 1203 (5th Cir. 1977) (Government's expert witness permitted to interpret intercepted telephone conversation and to give his opinion as to the defendant's role in a gambling organization); *Marx & Co., Inc., v. Diners' Club, Inc.*, 550 F.2d 205 (2d Cir. 1977), *cert. denied*, 434 U.S. 861 (1977) (trial judge committed error in permitting plaintiffs' securities law expert to give his opinion as to the legal obligation of the defendant under a certain contract and that the defendant's defense was unacceptable as a matter of law).

For example, in *Marx & Co., Inc., v. Diners' Club, Inc.*, the Second Circuit said:

> In the case at bar, however, [the expert witness'] objectionable testimony did *not* concern only the customary practices of a trade or business. Rather, he gave his opinion as to the legal standards which he believed to be derived from

> the contract and which should have governed Diners' conduct. * * *
>
> * * * It is not for witnesses to instruct the jury as to the applicable principles of the law, but for the judge. * * * The special legal knowledge of the judge makes the witness' testimony [on the law] superfluous.
>
> * * *
>
> It is for the jury to evaluate the facts in the light of the applicable rule of law, and it is therefore erroneous for a witness to state his opinion on the law of the forum. 550 F.2d at 509-510 (emphasis in the original).

In *Milton*, the Fifth Circuit correctly stated the meaning of Rule 704:

> Rule 704 abolishes the per se rule against testimony regarding ultimate issues of *fact*. By the same token, however, courts must remain vigilant against the admission of *legal* conclusions, and an expert witness may not substitute for the court in charging the jury regarding the applicable law. 555 F.2d at 1203 (emphasis added).

However, the Fifth Circuit's decision here upholds the admissiblity of testimony of a Government official giving his opinion as to the required legal standards of conduct. In so holding, the Fifth Circuit has permitted an expert witness to usurp the authority and responsibility of the trial judge. This decision sanctions the use of an expert to give his opinion and interpretation of the law and what it requires, and necessarily conflicts with the earlier federal appellate decisions cited above.

The Fifth Circuit here has misinterpreted Rule 704 and has sanctioned the use of expert opinion testimony in a manner not contemplated by the drafters of the rule. The Advisory Committee Note to Rule 704 states:

> The abolition of the ultimate issue rule does not lower the bars so as to admit all opinions. * * * These provisions afford ample assurances against the admission of opinions which would merely tell the jury what result to reach, somewhat in the manner of the oath-helpers of an earlier day.

See also, Marx & Co., Inc., v. Diners' Club, Inc., supra at 551 n. 17.

The opinion testimony here was particularly grievous to the petitioner because he contended that there were no specific FDA GMP regulations governing his conduct. The Government's expert attempted to create legal requirements based upon his own personal opinion, and the prosecution used this witness to bootstrap in a standard of conduct which did not exist in the black letter statutes and regulations. This misuse of expert testimony was compounded by the trial court's erroneous jury instructions. *Cf. United States v. United States Gypsum Co.*, ___ U.S. ____, 98 S.Ct. 2865, 57 L.Ed.2d 854 (1978).

Contrary to the dicta of the Fifth Circuit, this opinion testimony did not only prejudice the petitioner as to the conspiracy count, the false writing count, and the violations of Section 351(a)(2)(B), but the opinion that the petitioner's conduct failed to satisfy the FDA's requirements permeated the entire trial.

Rule 704 does not permit an expert to tell the jury what he thinks the law is or should be. The scope of Rule 704

concerning opinion testimony as to the *law* rather than *facts* is of continuing importance due to the overwhelming number of cases, both civil and criminal, which involve the interpretation and application of federal agency regulations.

The Fifth Circuit's decision here in effect allows a Government bureaucrat to create legal standards of conduct based upon his professional opinion and to so instruct the jury – encroaching upon the prerogatives which under our system of law are reserved for the Congress and the judiciary.

Therefore, this Court must grant certiorari in this case and, after further briefing and oral argument, reverse the lower court so as to resolve any doubt that expert opinion testimony which interprets the law or concludes what is required by the law is not permitted by Rule 704, Federal Rules of Evidence.

CONCLUSION

In view of the vital importance of the question presented and the considerations set forth above, this Court must grant this petition for writ of certiorari.

Respectfully submitted,

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APPENDIX A
IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

No. 77-5215

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

versus

ALFRED E. SMITH, and
MARVIN W. JOHNSON,
Defendants-Appellants.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA

(October 3, 1978)

Before GEE, FAY and VANCE, Circuit Judges

PER CURIAM

Alfred E. Smith and Marvin W. Johnson were the president and secretary, respectively, of Southwestern Plasma Center, Inc. They, the corporation and other individuals were charged in a sixteen count indictment with violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392, conspiracy to commit violations of that act and related offenses. They were tried by jury in the United States District Court for the Middle District of Florida.

Smith was convicted under all sixteen counts. He was sentenced to imprisonment for three years under Count One, the conspiracy count. He received a consecutive sentence of three years imprisonment under Count Two with execution of the sentence suspended during probation. Under each of the remaining counts he received a sentence to imprisonment for one year with the sentence to run concurrently with the sentence under Count One.

Eleven counts were submitted to the jury as to Johnson and he was found guilty under all eleven. He was sentenced to imprisonment for two years under Count One, two years under Count Two and one year under each of the remaining counts, with the sentence under all other counts to run concurrently with the sentence under Count One.

On appeal Smith and Johnson complain only in connection with the testimony of an expert witness, Dr. Sam T. Gibson. It is contended that Dr. Gibson was improperly allowed to testify as to his opinion and that the trial court also erred in unduly restricting his cross examination. The subject area about which Dr. Gibson testified concerned only five of the substantive counts and a portion of the conspiracy count. In practical effect, convictions under the remaining counts stand unchallenged.

Fed.R. Evid. 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

The admissibility of opinion testimony involves a matter within the trial court's discretion, which is subject to reversal only if manifestly erroneous. *United States v. Beaver*, 524 F.2d 963, 965 (5th Cir. 1975), *cert. denied*, 425 U.S. 905 (1976); *Keystone Plastics, Inc. v. C & P Plastics, Inc.*, 506 F.2d 960, 966 (5th Cir. 1975). Subject to the requirement that sufficient cross examination must be allowed to satisfy the sixth amendment, control of the conduct of cross examination is also a matter of the trial judge's discretion. *United States v. Ramirez*, 533 F.2d 138, 140 (5th Cir.), *cert. denied* 429 U.S. 884 (1976); *Fountain v. United States*, 384 F.2d 624, 627 (5th Cir.), *cert. denied* 390 U.S. 1005 (1967).

Our consideration of the record and the briefs and argument of counsel leads us to conclude that no reversible error was committed by the court below.

AFFIRMED.

APPENDIX B
IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

No. 77-5215

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

versus

ALFRED E. SMITH, and
MARVIN W. JOHNSON,
Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

ON PETITION FOR REHEARING
(October 30, 1978)

Before GEE, FAY and VANCE, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above entitled and numbered cause be and the same is hereby Denied.

ENTERED FOR THE COURT:

/s/ _____
United States Circuit Judge

APPENDIX C
IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

No. 77-5215

FILED
TAMPA, FLA
Nov. 9, 1978
Wesley R. Thies
Clerk

D. C. Docket No. 76-138-CR-T-K

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

ALFRED E. SMITH and MARVIN W. JOHNSON

Defendants-Appellants

Appeals from the United States District Court for the Middle District of Florida

---

Before GEE, FAY, and VANCE, Circuit Judges.

JUDGMENT

This cause came on to be heard on the transcript of the record from the United States District Court for the Middle District of Florida, and was argued by counsel;

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be, and the same is hereby, affirmed.

October 3, 1978

Issued As Mandate: Nov. 7, 1978

Copies to:
U.S. Attorney's
U.S. Marshall
U.S. Probation

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No. 78-935

In the Supreme Court of the United States

OCTOBER TERM, 1978

MARVIN W. JOHNSON, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

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In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-935

MARVIN W. JOHNSON, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

---

1. Petitioner was, during the indictment period, the secretary of the Southwestern Plasma Center, Inc., a commercial corporation in Florida that obtained human blood plasma, separated it into Source Plasma (Human) and Fresh Human Serum, and then sold those products (Pet. App. 1a; Tr. 346-347, 3134-3136, 3146).[1] Both Source Plasma (Human)

[1] "Pet. App." refers to the Appendix to the petition for a writ of certiorari. "Tr." refers to the official transcript of the trial in the United States District Court for the Middle Dis-

and Fresh Human Serum were drugs, as defined in section 201 of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. 321(g)(1)(B), and subject to the "current good manufacturing practice" requirements of Section 501 of that Act, 21 U.S.C. 351(a)(2)(B). The products were also "biological products" regulated under the Public Health Service Act, to be prepared in compliance with officially promulgated safety, purity, and potency standards. 42 U.S.C. 262(a) and (d).

To implement the drug manufacturing provisions of the Federal Food, Drug, and Cosmetic Act, the FDA promulgated regulations for use throughout the drug industry detailing good manufacturing practice. 28 Fed. Reg. 6385 (June 20, 1963), as amended 32 Fed. Reg. 15109 (Nov. 1, 1967), adopting 21 C.F.R. 133 *et seq.* (now 21 C.F.R. 210 *et seq.*). The regulations required manufacturers to insure, through their facilities, equipment, personnel, and drug components, that the drug has the safety, identity, strength, quality and purity it purports to possess. 21 C.F.R. 133.3-133.6 (now 21 C.F.R. 211.20, 211.30, 211.10 and 211.42). By 1973, the FDA had adopted more specific regulations for the procurement and handling of biological products, including Source

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trict of Florida, presently lodged with the court of appeals. "Tr.*" refers to the United States' copy of the transcript. The court reporter made one official transcript and several copies, but misnumbered the pages of all the copies. We regret that this memorandum refers to two differently paginated transcripts, but we do not have access to the official transcript for the additional references not included in our court of appeals briefs.

Plasma (Human) and Fresh Human Serum. 38 Fed. Reg. 32048 (November 20, 1973), adopting 21 C.F.R. 600, 610, and 640. These regulations required that every donation of Source Plasma (Human) or Fresh Human Serum be tested for hepatitis, 21 C.F.R. 610.40, and that every first-time donor of Source Plasma (Human) be given a medical examination by a qualified physician. 21 C.F.R. 640.63.

2. In 1976, a grand jury for the Middle District of Florida indicted petitioner, four other individuals, and the Southwestern Plasma Center on sixteen counts for various offenses committed from August 1973 to January 1975 in collecting, manufacturing, storing and shipping plasma and plasma products. The eleven charges ultimately pursued against petitioner consisted of (1) a conspiracy to violate the federal drug and false statement laws, in violation of 18 U.S.C. 371; (2) the making of a false statement in violation of 18 U.S.C. 1001; (3) two violations of Section 351 of the Public Health Service Act, 42 U.S.C. 262, by false labeling of containers of blood components; (4) three violations of Title 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(a), by the introduction of misbranded drugs into interstate commerce; and (5) four violations of Title 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(a), by the introduction of adulterated drugs into interstate commerce. The three misbranded drug charges alleged that the defendants placed labels on plasma and serum samples falsely stating that they were non-reactive to hepatitis. The four adulterated drug charges alleged that three

plasma samples and one serum sample were adulterated because they were not manufactured in compliance with current good manufacturing practice, 21 U.S.C. 351(a)(2)(B), and because of the presence of hepatitis, 21 U.S.C. 351(c).

At trial, the prosecution proved that certain unqualified Human Source Plasma donors were allowed to donate under inactive donors' names (Tr. 1075-1079, 1157-1159, 1455-1458). Petitioner signed forms stating he had physically examined donors, when in fact he had not (Tr. 801-802, 928-929, 1076, 1227-1232, 1423-1429). The Center's employees falsified and invented donor records (Tr. 1461-1468, 1779). Leftover parts of donors' samples were occasionally pooled into one plasma unit and attributed to an inactive or a rejected donor (Tr. 1066-1070*). Plasma testing positive for hepatitis was reported as destroyed but was in fact stored with healthy plasma and then shipped under a label asserting a negative reaction to hepatitis (Tr. 2295-2298, 2336-2342, 3258-3263, 3328-3336). Serum that had tested positive for hepatitis was shipped with the representation that it had tested negatively (Tr. 2384, 2622-2623, 2987-2988).

The prosecution's twenty-sixth witness was Dr. Sam T. Gibson, an expert in plasmapheresis and familiar with the industry's practices during the indictment period (Tr. 2750-2751*). After preliminary questioning, Dr. Gibson responded to nine questions concerning the safety, identity, strength, quality and purity of products manufactured by a plasmapheresis firm (Tr. 2758-2772*). Dr. Gibson stated that, in his

opinion, a plasma donor should be examined by a physician prior to his first donation to insure the safety of both the donor and his product (Tr. 2764*). Each sample should be tested for hepatitis and accurate donor and testing records should be maintained in order to trace any contamination (Tr. 2759*, 2768-2769*). At petitioner's insistence, Dr. Gibson did not use the phrase "good manufacturing practice," and was not permitted to refer to the FDA's regulations (Tr. 2723-2724*, 2736-2737*). His personal opinions comported with the two sets of FDA regulations.[2]

In the closing instructions to the jury, the court observed that, with respect to petitioner, only the four adulteration counts involved the good manufacturing practice of the plasmapheresis industry (Tr. 4200*). The court recited the FDA regulations and

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[2] Dr. Gibson testified that any first time donor of plasma should be examined by a physician prior to plasmapheresis (Tr. 2764*). He did not qualify his opinion based on the particular plasma by-product. The FDA regulations required that only first time donors of Source Plasma (Human) be examined by a doctor. 21 C.F.R. 640.63. There was no FDA regulation requiring examination of a first time donor of Fresh Human Serum. Only one of the eleven counts against petitioner, however, involved adulterated serum (Count 15). The government charged that the serum was adulterated not merely because it was not manufactured in compliance with good manufacturing practice but also because it was contaminated by hepatitis. The evidence bore out the hepatitis charge (Tr. 2408-2414, 2439). Moreover, aside from the medical examination issue, there were other bad manufacturing practices in association with the serum sample, notably the method of pooling serum samples in such a way that hepatitis could result (Tr. 2443-2450*, 2477-2484*).

then instructed the jury that, in assessing whether defendants violated the good manufacturing practice standard of the Federal Food, Drug, and Cosmetic Act, they could consider "the Federal Regulations, the expert testimony and * * * all the evidence in the case * * *" (Tr. 4189-4200*).

The jury convicted petitioner on all eleven counts and the district court sentenced him to two two-year sentences and nine one-year sentences, all to run concurrently (Pet. App. 2a). On appeal, the court of appeals noted that petitioner's sole ground for appeal —an objection to Dr. Gibson's testimony—concerned only some of the counts, and that the convictions under the remaining counts were unchallenged (*ibid.*). It affirmed the convictions on the challenged counts, concluding that the district court's admission of expert opinion testimony did not constitute reversible error (Pet. App. 3a).

3. The decision of the court of appeals is correct, raises no novel issue, and does not conflict with any decision of this Court or of any court of appeals. Accordingly, the case does not warrant further review.

Dr. Gibson described the plasma collection process, the health dangers to the plasma donor and subsequent recipients of plasma products, and methods that, in his opinion, could minimize those dangers. That testimony was surely of assistance to the jurors in determining if defendants' plasmapheresis enterprise was operated safely. The testimony gave tangible meaning to the FDA regulations. Admitting it

was consistent with Rule 702, Fed. R. Evid., with invites expert testimony if it will assist the jury to understand a contested issue. This Court has consistently ruled that "the District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true in the case of expert testimony." *Hamling* v. *United States*, 418 U.S. 87, 108 (1974). Under the circumstances, the court of appeals correctly concluded that the district court's decision to admit Dr. Gibson's testimony hardly could be veiwed as an abuse of its discretion constituting manifest error (Pet. App. 3a).

Petitioner's sole basis for challenging the rulings of both courts below is a novel and unfounded reading of Rule 704, Fed. R. Evid. That rule permits opinion testimony, even where it embraces an ultimate issue to be decided by the jury, provided that the expert does not "substitute for the court in charging the jury regarding the applicable law." *E.g.*, *United States* v. *Milton*, 555 F.2d 1198, 1203 (5th Cir. 1977). Dr. Gibson's testimony neither referred to the FDA regulations nor used the phrase "good manufacturing practice." It is therefore difficult to conceive how the jurors could have viewed the expert opinion testimony as instructions as to the law. The court left to the jury determinations of what was good manufacturing practice in the plasmapheresis industry and whether defendants met that standard. For assistance in making those determinations, the jury was permitted to consider the FDA regulations, the expert testimony, and all the evidence. Those instructions in effect

informed the jury that Dr. Gibson's opinion of appropriate industrial methods was not necessarily the legal standard of good manufacturing practice. This was the appropriate course in dealing with regulations and expert testimony in cases raising good manufacturing practice issues. *See, e.g., United States* v. *Dianovin Pharmaceuticals, Inc.*, 342 F. Supp. 724, 728 (D.P.R. 1972), aff'd, 475 F.2d 100 (1st Cir.), cert. denied 414 U.S. 830 (1973).[a]

[a] *Marx & Co., Inc. v. Diners' Club, Inc.*, 550 F.2d 505 (2d Cir.), cert. denied, 434 U.S. 861 (1977) does not support petitioner's conclusion that Dr. Gibson's testimony should be stricken under Rule 704, Fed.R.Evid. (Pet. 12-14). To the contrary, the court in *Marx*, while striking testimony of a witness which purported to give the definitive interpretation of a contract, observed that testimony concerning the ordinary practices of an industry is admissible "to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry." *Id.* at 509. Dr. Gibson's testimony in the present case gave the jury a better factual understanding of the risks of plasmapheresis and the practices of that industry without instructing the jury on the legal standard of care.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

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